headache, eye irritation, cough cold etc. which subsides subsequently to the withdrawal of use of the repellent.

(c) According to ICMR, Central Insecticide Board (CIB) which regulates the use of insecticides, bio-larvicides and repellents in the country has an inbuilt mechanism to evaluate the bio-efficacy & toxicity of insecticides/ repellents to non-targed organism including human subjects and allow registration and use of only those insecticides/repellents which fulfill the standard bio-efficacy and safety norms.

**Clinical trial on patients**

2936. SHRI N.K. PREMACHANDRAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the pre-conditions and norms prescribed for conducting clinical trial on patients;

(b) whether it has come to the notice of Government that Regional Cancer Centre, Thiruvananthapuram, in collaboration with the John Hopkins University in Baltimore, United States has used banned drugs and subjugation of patients rights in the clinical trial;

(c) if so, the action taken by Government;

(d) whether any inquiry has been conducted in this regard; and

(c) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR): (a) Requirement for conducting clinical trial on patients for import and manufacture of new drug is prescribed in Schedule Y of Drugs and Cosmetic Rules, 1940 which includes evaluation of pre-clinical/clinical data on safety and efficacy of the drug. It is desirable that protocols for clinical trial be reviewed and approved by the ethical committee of the Institution conducting the trial.

(b) to (e) An Enquiry Committee has been constituted by the Director General of Health Serves to Enquire into the allegations regarding reported use of unauthorised drugs on cancer patients for purposes of clinical trials by Regional Cancer Centre, Thiruvananthapuram. The Report of the Committee is awaited.